510(k) SUMMARY

The 510(k) Summary is submitted as required by section 807.92(a)

SPONSER: Volcano Corporation
3721 Valley Centre Dr., Suite 500
San Diego, CA 92130

CONTACT/ SUBMITTER: Marcus Garcia
Regulatory Affairs Specialist
Volcano Corporation
1 Fortune Dr.
Billerica, MA 01821
Phone: 978-439-3312
Fax: 978-262-0035
email: mgarcia@volcanocorp.com

DATE SUBMITTED: November 26, 2013

DEVICE: CORE™/CORE™ Mobile Precision Guided Therapy Systems

Trade Name: Volcano CORE™ Control Pad, Accessory to the Volcano CORE™/CORE™ Mobile Precision Guided Therapy Systems

Common Name: Ultrasonic pulsed echo imaging system

Classification and Product Codes:

CFR Number	Class	Product Code
892.1560 Ultrasonic pulsed echo imaging system	II	IYO
870.1110 Blood Pressure Computer	II	DSK
870.2900 Patient Transducer and Electrical Cable	II	DSA

PREDICATE DEVICE: K13314, Volcano s5™/s5i™ CORE™ and CORE™ Mobile Series Precision Guided Therapy Systems

DEVICE DESCRIPTION:
The Volcano CORE™ Series Precision Guided Therapy Systems are currently available in 2 configurations: (1) a tower or a portable model, (2) an integrated model.

The Volcano CORE™ Precision Guided Therapy Systems are the integrated configurations that are integrated in the catheterization (cath) laboratory, meaning that the CPU is located outside the cath lab and the controls and accessories are cabled in a trench under the floor into the cath lab for use on the patient. Cables from the CPU enter the cath lab through trench and are consolidated through the Connection Box located in the cath lab which then distributes connections to all the CORE™ accessories and bedside peripherals.

The CORE™ Mobile tower systems are the tower/portable (roll-around or mobile) versions of the integrated system. These systems can be rolled into the cath lab itself and the accessories and bedside peripherals directly connect to the system.

There are two (2) operating modes available on both the integrated as well as the tower models of the Volcano Precision Guided Therapy Systems, namely: (1) the Intravascular Ultrasound (IVUS) imaging mode and (2) the Fractional Flow Reserve (FFR) pressure mode.

When operating the IVUS mode, the system console gathers and displays high-resolution intraluminal images that can be analyzed both quantitatively and qualitatively. When operating in pressure mode, the system acquires intraluminal data from a pressure guidewire while simultaneously taking aortic pressure data from the established ECG/EKG catheterization lab equipment. Catheters and guidewires are connected to the system via the Patient Interface Modules (PIMs).

As an accessory to the CORE™ Systems, the Volcano CORE™ Control Pad is intended to be a secondary controller in the Volcano CORE™ Precision Guided Therapy Systems (integrated and mobile systems). It is intended to be used in the exam room, in the sterile field at the bedside in the exam room, in the control room, or on the mobile cart. Images, data, and case navigation controls are relayed to and from the CORE™ Control Pad display via the system central processing unit (CPU). These images, data and controls are presented in a graphical user interface (GUI) displayed on the touch screen of the CORE™ Control Pad. The GUI displayed on the screen of the CORE™ Control Pad will represent, but may not duplicate exactly, the intravascular ultrasound images displayed on the main system monitor. The relayed case navigation controls are intended to allow the user to navigate IVUS and FFR cases and to make measurements on intravascular ultrasound images that are presented on the primary system display. The CORE™ Control Pad touch screen display is an adjunct to the main display on the Volcano CORE™ Series Intra-vascular Imaging and Pressure System. The CORE™ Control Pad is not intended as a standalone diagnostic tool.

INDICATIONS FOR USE

The Volcano CORE™/CORE™ Mobile Series Intravascular Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary

arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo® is indicated for qualitative blood flow information from peripheral and coronary vasculature: flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

VH® IVUS intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The Volcano VH IVUS System is intended to semi-automatically visualize boundary features and perform spectral analysis of RF ultrasound signals of vascular features that the user may wish to examine more closely during routine diagnostic ultrasound imaging examinations.

The pressure feature is intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures.

Rotational 45MHz feature is intended for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vasculature. As an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures. The pullback feature of the PIMr withdraws the imaging core within the protective sheath for a maximum of 15 cm.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The proposed device is identical to the currently marketed device except for the addition of a new optional accessory, the Volcano CORE™ Control Pad. The Volcano CORE™ Control Pad acts as secondary controller in the Volcano CORE™ Precision Guided Therapy Systems (integrated and mobile systems). The technological characteristics, fundamental scientific technology, and indications for use remain unchanged.

PERFORMANCE DATA:

Applicable testing was performed as require by the Quality System to evaluate the modification to the Volcano CORE™ Systems. The following tests were conducted:

- Software Verification and Validation
- Simulated Use Validation
- Electrical Safety

- Electromagnetic Compatibility
- Packaging Validation
- Extreme Temperature and Humidity
- Drop Test
- Mounting Load
- Tensile Load CCP Pig Tail Cable
- Acoustic Noise Level Test CCP
- Reliability HALT (Highly Accelerated Life Testing)
- Mean Time Between Failure (MTBF)

The test results were found to be acceptable by the respective test plans and protocols.

Biocompatibility and sterilization testing was not required as the proposed accessory does not come in contact with the patient or any fluid path.

Conclusion:
Completion of these tests concluded that the proposed Volcano CORE™ Systems are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 20, 2013

Volcano Corporation
Marcus Garcia
1 Fortune Dr
Billerica, MA 01821 US

Re: K133641
Trade/Device Name: Core Control Pad, Core Series SW v3.4 Installation Kit, Core, Core Mobile
Regulation Number: 21 CFR 892.1560
Regulation Name: System, Imaging, Pulsed Echo, Ultrasonic
Regulatory Class: Class II
Product Code: IYO
Dated: November 26, 2013
Received: November 29, 2013

Dear Marcus Garcia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K133641

Indications for Use

510(k) Number (if known): K133641

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Prescription Use ____X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-the Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Digitally signed by Owen P. Faris -S
Date: 2013.12.20 15:31:28 -05'00'